Australian Government
Department of Health
Therapeutic Goods Administration

Regulatory update from the Medical Devices Authorisation Branch

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TGA Health Safety Regulation

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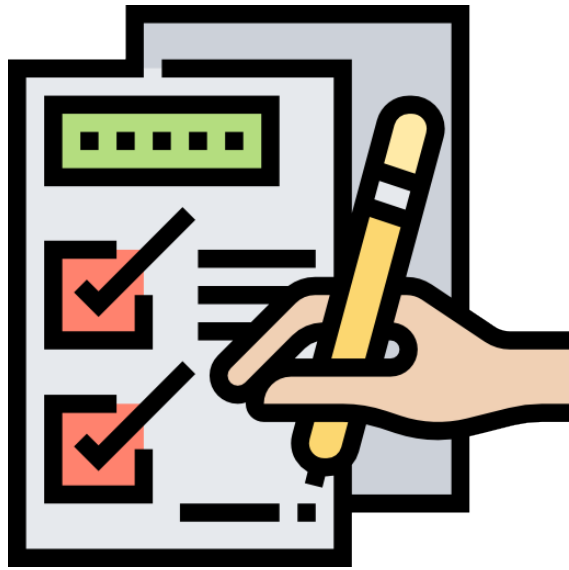
This presentation

The Government is in caretaker mode and in accordance with caretaker conventions I will be limiting my statements today to technical and factual issues around the regulatory framework and matters of administration of medical device regulation.

- Device applications over the last year
- COVID-19 tests
- Conformity Assessment changes in 2021
- Aligning with EU MDR and IVDR
- Other Pre-market reforms
- Post-market reforms
- Other work underway

Medical device applications

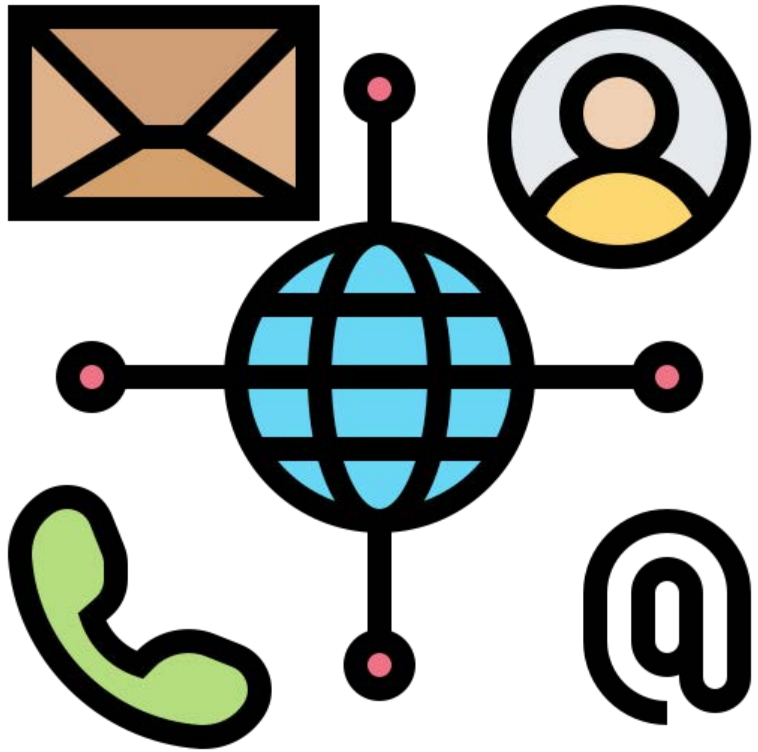
- **About 95% of ARTG entries (excluding class I) use approvals from comparable overseas regulators**
  - 85% use EU approvals
- **2020-21 application numbers**
  - medical devices: Class I (3,950), Class IIa (1,579), Class IIb (646), Class III/AIMD (521)
  - IVDs: Class 1 (93), Class 2 (57), Class 3 (128) and Class 4 (12)
- **All conformity assessments processed within the legislated timeframe of 255 days**
  - conformity assessment times for new devices increased by 22% in 2021
  - 2020-21: 328 applications, mean 157 days; 2019-20: 308 applications, mean 129 days
- **Resources directed to COVID-19 device applications**
  - 69% of 2020-21 IVD applications audited vs. 39% in 2019-20
  - a significant increase in applications for COVID-19 tests, face masks and PPE



Medical Devices Information Unit

- So far, in 2022 the MDIU has responded to:
  - 5,869 calls
  - 11,648 emails

- The hot topics in 2022 have included:
  - updates on applications
  - COVID-19 tests, especially RATs
  - Reforms, including notifications

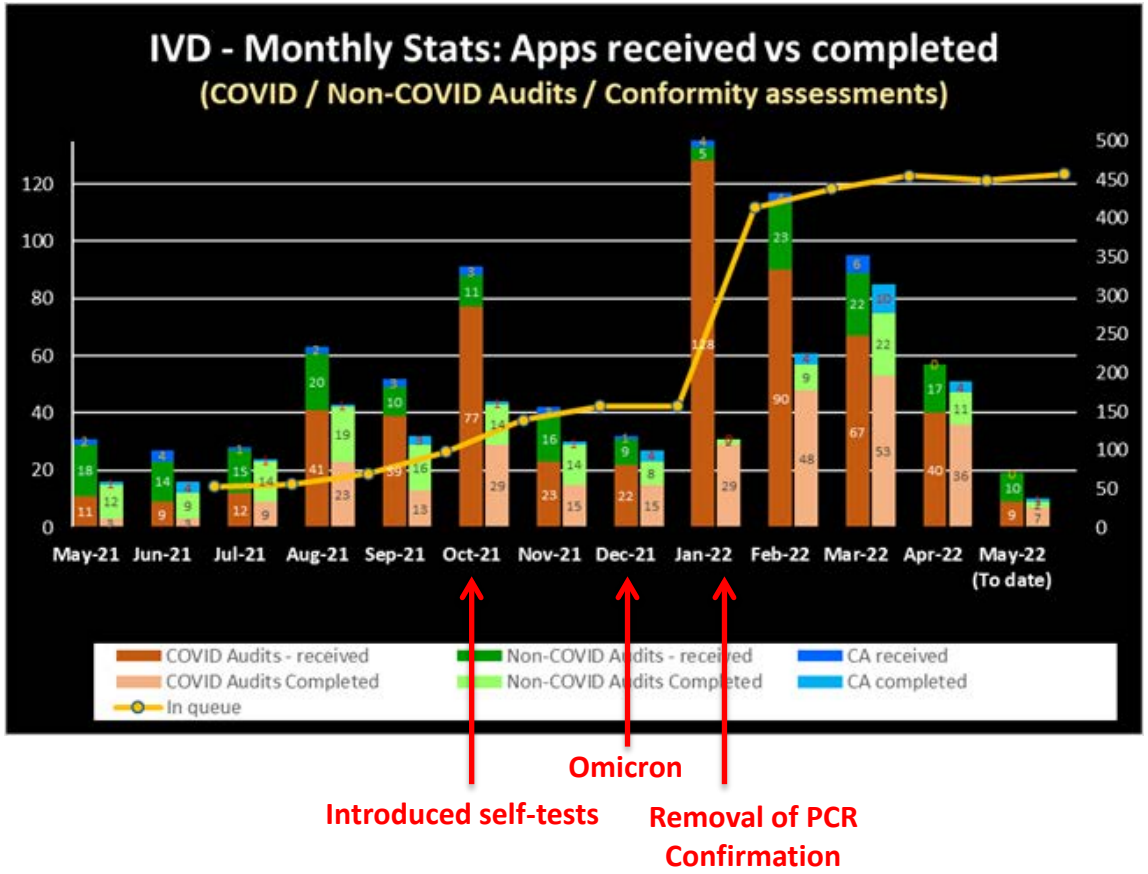


Approving COVID-19 tests

- **We have assessed many RATS and several multiplex respiratory tests**
  - developed detailed guidance, checklists and website content
  - dedicated email inbox, enquiries line and “hand holding” to help new sponsors
  - increased pre-market IVD assessment team
  - streamlined assessment processes, letter and report templates
  - diverted resources from BAU and other areas of the TGA
  - it did slow review of some other IVDs and devices
  - targeted training of new assessors, staff working evenings and weekends
- **Priority for COVID-19 applications is now multiplex flu/COVID-19 PCR testing**
  - to ensure maximum capacity for laboratories in preparation for winter

Approving COVID-19 tests

- As of 15 May 2022, 94 COVID-19 rapid antigen tests have been approved
  - 47 self-tests, 47 Point-of-Care tests
- 60% of completed RAT applications have either lapsed, been withdrawn or rejected
- COVIDtests@tga.gov.au inbox received 2,100 email enquiries per month in 2022



Focus on combination RATs

Guidance for Seasonal Influenza rapid antigen tests is coming soon

- Historically there are performance challenges with some influenza RATs
- Updated clinical performance requirements and risk mitigation strategies
- Influenza-specific requirements also apply to combination influenza /COVID-19 RATs

- Limits of Detection and analytical reactivity requirements consistent with US FDA guidance
- Conditions of inclusion for monitoring of seasonal changes in circulating influenza strains, with annual evaluation

Post-Market Review of COVID-19 test kits and Variants of Concern

RATs (47 Self-tests and 47 Point-of-care tests in ARTG as of 15 May 2022)

- The Doherty Institute is undertaking laboratory testing for the TGA:
  - checking analytical sensitivity (Limit of Detection (LoD)) - the lowest concentration an analyte can be detected is within the WHO level for Wild-type, Delta, and Omicron variants.
  - WHO acceptable LoD of SARS-CoV-2 antigen tests is 100 to 1,000 $TCID_{50}$/mL
  - results will be sent to each sponsor and published on the TGA website as they become available (www.tga.gov.au/post-market-review-antigen-and-rapid-antigen-tests)

Conformity assessment changes in 2021

Change applied from 28 July 2021

Regulation 4.1 repealed

Regulation 4.1 required TGA conformity assessment for specific high risk devices:

- medical devices containing medicines or materials of animal, microbial, recombinant or human origin
- Class 4 in vitro diagnostic (IVD)

NOW Sponsors can provide conformity assessment documents issued by notified bodies designated by a member state of the European Union to support an application for inclusion in the ARTG for these devices.

Regulation 5.3 amended

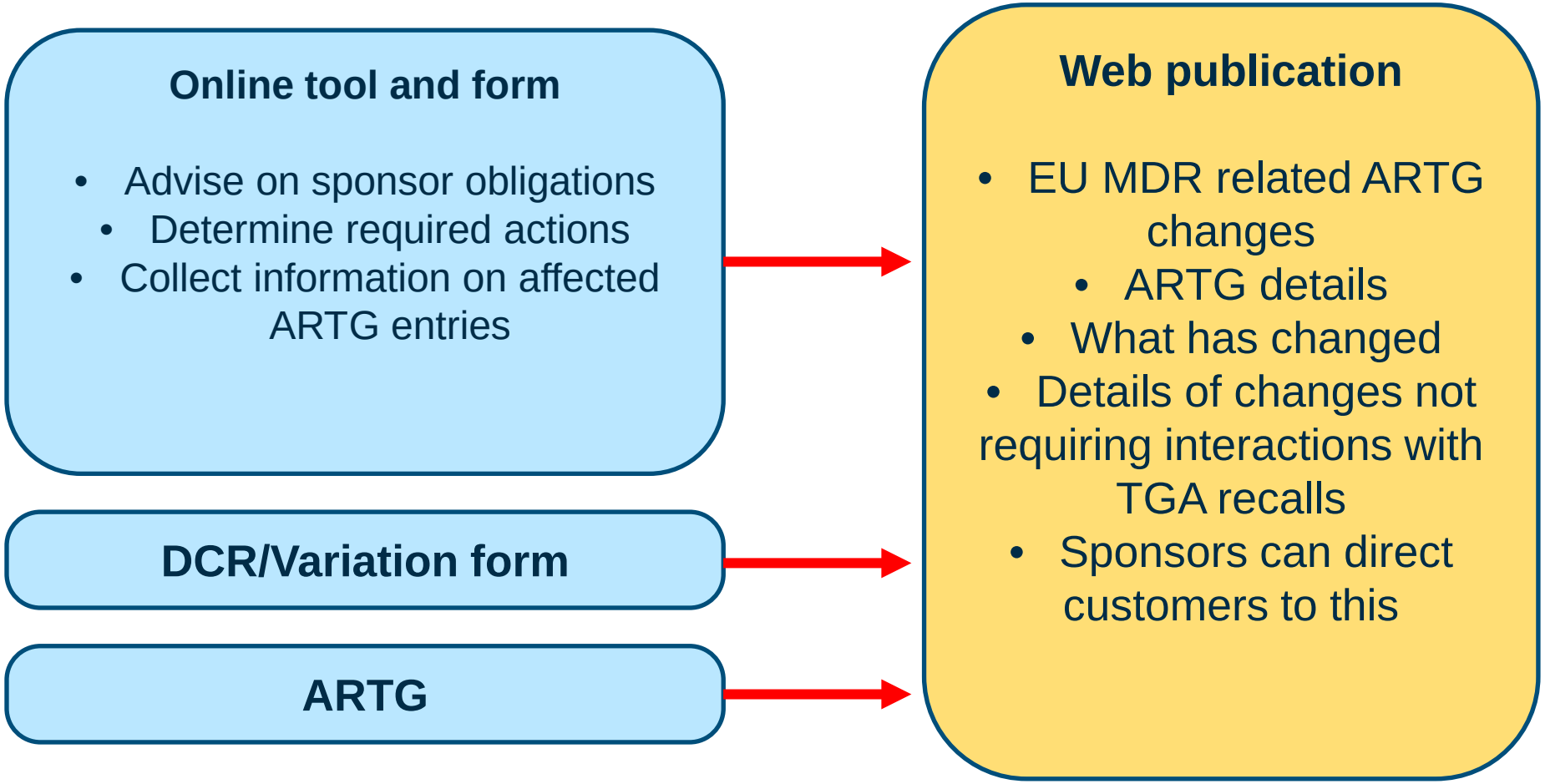
Regulation 5.3 allows the TGA to audit applications for inclusion in the ARTG

- Audits are mandatory (and audit fees apply) for
  - Class III, AIMD, specified Class IIb medical devices
  - Class 4 IVDs and a number of specified Class 3 IVDs

  unless supported by a conformity assessment from TGA, or Australian conformity assessment body, or **issued under the European MDR / IVDR**
- Any device may be selected for audit (no audit fee applies for discretionary audit)

This ensures devices meet Australian regulatory requirements prior to approval for supply in Australia

Proposed EU MDR notification process



Aligning with EU IVDR

Acceptance of ISO 13485 certificates has been extended for IVD applications

- Therapeutic Goods (Medical Devices - Information that Must Accompany Application for Inclusion) Determination 2018 (legislation.gov.au) updated in line with previous industry discussions
  - https://www.legislation.gov.au/Details/F2021C00894
- All new Class 2 & 3 IVDs were extended until 26 May 2023 (i.e. by 12 months)
- Thereafter, for CE marked IVDs already in supply and accompanied by a valid EU declaration of conformity supporting legal supply in EU prior to May 2022:
  - ISO certificates will continue to be accepted for Class 3 IVDs until 26 May 2026
  - ISO certificates will continue to be accepted for Class 2 IVDs until 26 May 2027
- Updated Determination will be published in near future

Action Plan for Medical Devices – released April 2019

- Three-part strategy:
  - Improve how new devices get on the market
  - Strengthen monitoring and follow-up of devices in use
  - Provide more information to patients about devices they use

- Accelerated patient-focussed and transparency reforms already underway
- Individual initiatives subject to public consultations (taking into consideration EU reforms and timeframes)
- Decisions on new policies/regulations always remain with government
- Focus to date has been on pre-market – now shifted to post market reforms

Companion Diagnostics (CDx)

- **Transitional arrangements**
  - the term ‘IVD companion diagnostic’ is defined in the **Therapeutic Goods (Medical Devices) Regulations 2002** and came into effect on 1 February 2020
  - definition aligns with US FDA and EU IVDR definitions
  - class 3 IVDs are subject to separate ARTG entries for each CDx
  - existing transitional arrangements set to end 30 June 2022, shortly after the application date of the EU IVDR (26 May 2022)
  - Europe extended transition for Class C (Class 3) IVDs until 26 May 2026
  - incoming government would need to decide whether to extend transition

- **Introduction of CDx framework immediately prior to the pandemic resulted in poor uptake as we approach the end of the assigned 18-month transition period.**

Software-based medical devices

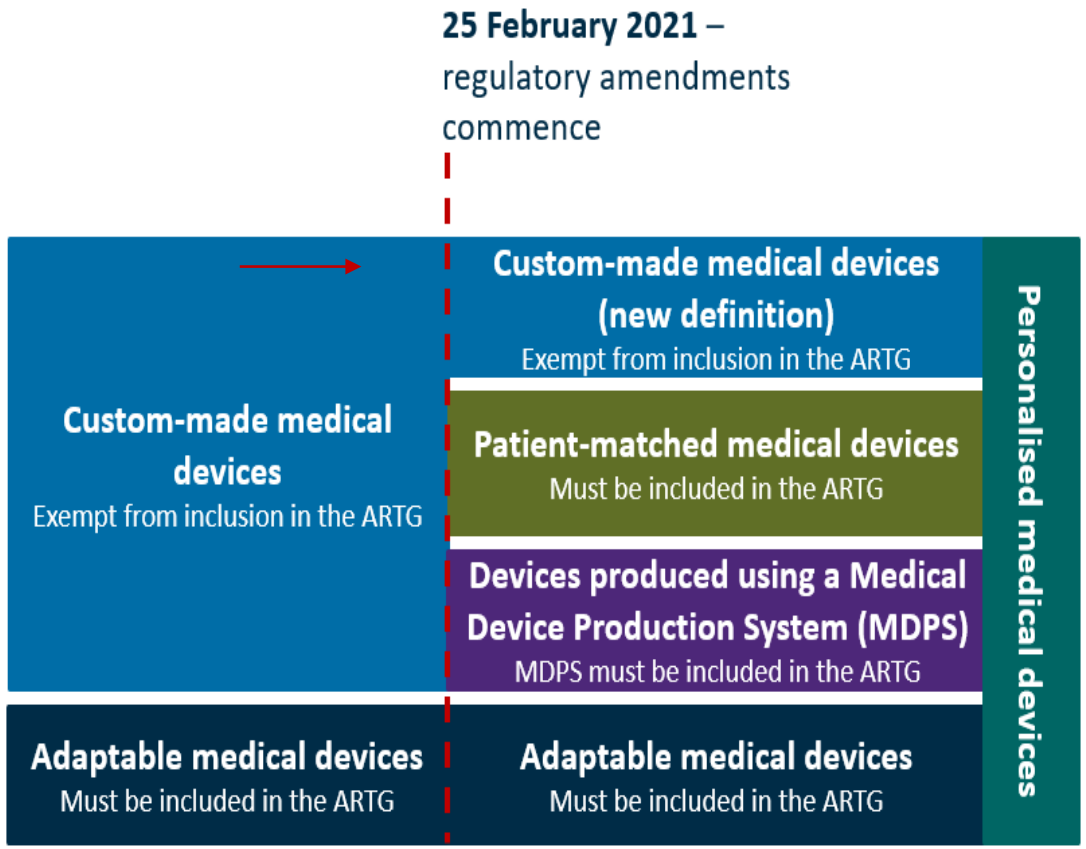
- Reforms introduced 25 February 2021
  - classification rules and Essential Principles changed (e.g. cybersecurity & version control)
  - ARTG exemption for certain clinical decision support software (strict criteria, notification required)
  - lower risk software exempted (15 categories)

- Notification period for transitioning devices ended 25 August 2021, transition ends November 2024

- Guidance published, ongoing education and engagement

Personalised medical devices

- **25 February 2021:** new personalised medical devices framework started
- **25 August 2022:** transition notification period will close
- **1 November 2024:** an application for inclusion in the ARTG must be made for all transitioning patient-matched medical devices by this date



Reclassification of certain medical devices

- Reforms introduced 25 November 2021
- Notification period for transitioning devices **ends 25 May 2022**, transition ends November 2024
- Guidance published, ongoing education and engagement

Reform	Old class	New class
Active medical devices for therapy with diagnostic function	IIa or IIb	III
Spinal implantable medical devices	IIb	IIb or III
Devices used in direct contact with the heart, central circulatory system (CCS), or central nervous system	IIa	III
Medical devices that administer medicines or biologicals by inhalation	I or IIa	IIa or IIb
Active implantable medical devices (AIMD)	AIMD	III
Medical devices that are substances introduced into the body via body orifice or applied to the skin	I or IIa	IIa, IIb, or III

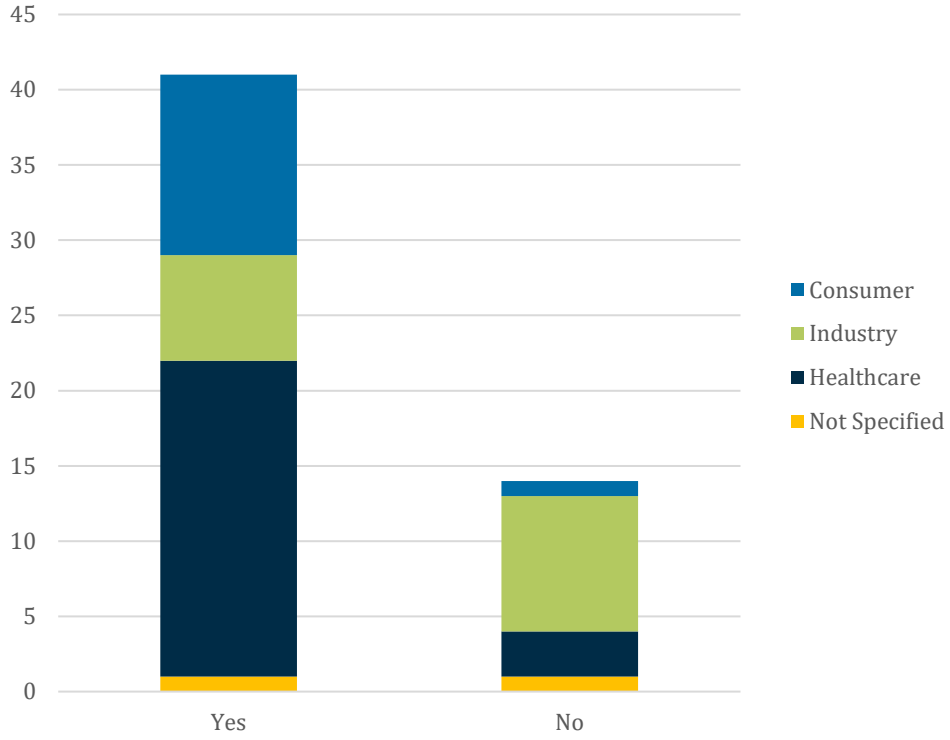
Post market reforms:
Proposed Enhancements to Adverse Event Reporting (2020 Consultation Paper)

- **Make changes to the current adverse event reporting exemptions**
  - targeted consultation and workshops progressing

- **TGA inspections and audits of sponsor activities/premises**
  - only 15% of sponsors have reported an adverse event to the TGA
  - pilot medical device vigilance program to progress in 2022
  - to improve awareness of responsibilities and ensure compliance with reporting obligations

Proposed mandatory reporting of medical device adverse events by healthcare facilities

- Early 2021: Discussions with hospitals, peak bodies, state governments, Australian Commission on Safety and Quality in Health Care and international regulators
- Oct-Dec 2021: Public feedback on Discussion Paper
- 56 responses received – submissions published
- **The TGA will work closely with the ACSQHC, state governments, private and day hospitals to progress mandatory reporting**
  - further discovery work on IVD adverse event reporting within healthcare settings
  - reviewing legislation, regulation and standards to identify existing implementation mechanisms

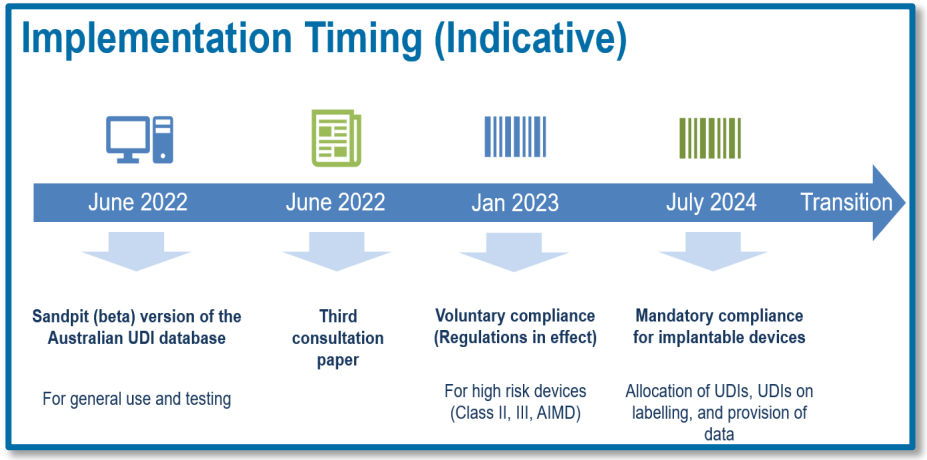


Australian Conformity Assessment Bodies (AU CABs)

- Therapeutic Goods Act amended in 2017 to enable TGA to designate Australian CABs
- Provides an alternative assessment pathway for manufacturers of medical devices to undergo assessment
  - potentially providing faster timeframes for device supply
  - guidance and application forms available on the TGA website
  - requirements largely adopted from the European Regulations and leverages IMDRF guidance on competency requirements for CABs
- TGA has not received any applications to date

Unique Device Identification (UDI)

- Regular webinars sharing global UDI experience
- “Triggers” Working Group - final report produced
- New GMDN codes updated daily into TGA systems
- Technical Working Group established to focus on data interoperability and machine to machine provision/use of data
  - ‘sandpit’ (beta) release in June 2022 – to enable early use and feedback before voluntary compliance begins
  - early Adopter Projects (Qld Health and Vic Western Health)
- ARTG / UDI data alignment work being planned
- Third consultation on regulatory framework proposed for June 2022



Advisory Committee on Medical Devices (ACMD)

- The ACMD has meet twice in 2022, on 10 February and 7 April. The next meeting will be held on 9 June 2022.

- ACMD provided advice on:
  - applications for novel medical devices and the quality of clinical studies performed
  - acceptance of claims of substantial equivalence between a new device and an established comparator product
  - management of emergent post-market signals
  - new TGA guidelines for Industry being drafted

International work & IMDRF

- **IMDRF IVD WG reviewing IVD clinical evidence guidelines**
- **IMDRF Regulated Product Submission WG – reviewing Table of Contents documents** aims to provide consistent formats for medical devices and IVD electronic data submissions to regulators
- **IMDRF Good Regulatory Review Practices WG** is developing a draft Product Assessment Report template for conformity assessment bodies
- **IMDRF Adverse Event WG** is improving and harmonizing the terminology and systems used to code adverse event information
- We are working to recognise Health Sciences Authority (HSA), Singapore as a ‘comparable overseas regulator’ (soon)
- Also liaising with UK Medicines and Healthcare products Regulatory Agency (MHRA) about formalising post-Brexit arrangements

Questions

- **Medical Devices Information Unit**
  - Monday to Friday, 8:30am – 5:00pm (AEST)
  - phone: 1800 141 144
  - Email: devices@tga.gov.au

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